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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,353	07/18/2003	Tae-Won Kang	P23973	2573

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EXAMINER	
HANLEY, SUSAN MARIE	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
08/10/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/621,353	KANG ET AL.	
	Examiner	Art Unit	
	Susan Hanley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,7-9,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,7-9,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and reply filed 4/11/07 are acknowledged.

Claims 1, 2, 4, 7-9, 11 and 12 remain under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The use of the trademarks, DIAION SP207, DIAION SP700, DIAION SP825, DIAION SP850, DIAION HP2MG , AMBERLITE XAD 4, AMBERLITE XAD 7, AMBERLITE XAD 1600T, AMBERSORB 563, AMBERSORB 572, AMBERSORB 600, Lewatit VP OC 1064, Lewatit VP OC 1066 and Lewatit EP 63, DIAION SK1B, DIAION PK216, DIAION CR11, DIAION CR20, DIAION UBK555 (Mitsubishi Chemical), TRILITE SPC 160H, TRILITE SPC 180H, TRILITE SPC 400LH, AMBERLITE 200C Na, AMBERLITE CG50, AMBERLITE CR1310 Na, AMBERJET 200H, AMBERLYST 131 WET, AMBERLYST 232 WET, Lewatit VP OC 1800, Lewatit VP OC 1812, Lewatit MDS1368 Na, Lewatit K1221, PUROLITE PCR833CA, PUROLITE C145, MFG 210 and MFG 250, SK-GEL ODS S15/30, Flash KP-C18-HS, DAISOGEL 3001A, and DMS DM 1020 has been noted in this application. They should be capitalized wherever it appears *and be accompanied by the generic terminology*.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The new matter rejection of the last Office action is withdrawn in light of the amendment to the specification which removed the generic language. However, the lack of generic language

forces the reinstatement of the original objection to the specification. It is suggested that the trademark names and the generic terminology can be joined if Applicant makes a showing (e.g., documentation) that the generic name of a trademarked resin was inherent at the time of the instant invention.

Claim Rejections - 35 USC § 112

Claims 1, 2, 4, 7-9, 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 is drawn, in part, to a purification step under (ii) that requires a catalytic resin, a cation exchange resin or a chelate resin. The specification, as filed, fails to describe what is meant by a "catalytic resin." "Catalytic" implies that the resin catalyzes some kind of reaction on the compound with which it comes in contact during the chromatographic step. If this is the meaning of a "catalytic resin" the specification, as filed, fails to disclose what reaction is catalyzed on the teicoplanin A2 as it comes into contact with the catalytic resin. The instant specification is directed to purification and lacks disclosure regarding any step that involves a reaction catalyzed by a resin. If the meaning of "catalytic resin" is different than a resin that effects a reaction during the chromatographic step, the skilled artisan would have no description from specification, as filed, to determine the content or purpose of the catalytic resin. Because the claims encompass a type of resin that is neither contemplated nor disclosed by the as-filed disclosure, it is clear that applicant was not in possession of the full scope of the claimed subject matter at the time of filing.

Claims 1, 2, 4, 7-9, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected because the phrase "catalytic resin" is vague. It is unclear what it is intended to catalyze.

Claim 2 is rejected because the meaning of an "adsorbent resin" is unclear. Claim 2 recites that a synthetic adsorbent can be a styrene/divinyl benzene ion exchange resin (last recitation of the Markush group). A resin of this type is disclosed by Glass et al. (US 4,845,194). Dow XFS-43278.00 is a sulfontated co-polymer of styrene and divinylbenzene that is microporous and a strong acid-cation resin (col. 3, lines 1-24). This resin appears to meet the definition of a adsorbent resin of part (i) of claim 1 as well as the limitation of a cation exchange resin, as recited in part (ii) of claim 1. Therefore, the meaning of an adsorbent resin is vague and indefinite.

Claim 7 is rejected because the term "it" in line 2 of the claim lacks antecedent basis in claims 7 or claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 7-9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawai et al. (US 6,391,851) in view of the combination of Restelli et al. (US 5,539,087), Glass et al. (US 4,845,194), Borghi et al. (US 4,542,018) and Strazzolini et al. (US 4,594,187). Glass and Borghi were cited in the IDS filed 3/15/06.

Sawai et al. discloses that vancomycin-type antibiotics are usually manufactured by a multi-staged process wherein a fermentate containing the antibiotic has been purified by a number of methods including contacting the fermentate with an adsorbent-type resin that is a porous nonionic styrene-divinylbenzene copolymer. Vancomycin-type antibiotics can also be purified by adsorption onto alumina, or absorption onto an ion exchange resin in which a carboxymethyl group is introduced into a synthetic polymer gel having a hydrophilic hydroxyl group. Sawai recommends, that if necessary, two or more purifying methods may be combined. Sawai names teicoplanin A2 as a vancomycin-type antibiotic (col. 1, lines 10-20). Therefore, Sawai teaches that the ordinary artisan would have known that purification scheme for vancomycin-type antibiotics are well known in the art and that it would have been obvious to the ordinary artisan to combine purification techniques that are standard in the art. Further, Sawai teaches that a common first purification step is contacting

an antibiotic-containing fermentate with an adsorbent-type resin that is a porous nonionic styrene-divinylbenzene copolymer.

Sawai does not teach the purification of teicoplanin A2 by combining an adsorbent resin chromatographic steps with subsequent chromatography steps on an exchange resin and reversed phase HPLC with the claimed solvent systems.

Restelli discloses that glycopeptide-type antibiotics can easily be separated from fermentate salts by desalination through a non-inorganic macroreticular cross-linked resin such as Amberlite XAD-7™ wherein the antibiotic is absorbed from the aqueous mixture and then eluted with aqueous acetone (col. 10, lines 46-55).

Glass discloses an improvement for the purification of vancomycin-type glycopeptide antibiotics which comprises co-mingling the fermentation medium in which the antibiotic is produced with a polystyrene divinylbenzene resin, separating the resin from the medium and eluting the antibiotic from the resin. Preferably the resin is Dow XFS-43278.00, which is a sulfontated co-polymer of styrene and divinylbenzene that is microporous. The resin is also a strong acid-cation resin with low cross-linkage (col. 3, lines 1-24). The disclosure of a cation exchange resin meets, in part, part (ii) of claim 1 which is related to the second step of the claimed method. Glass discloses that teicoplanin or any of the teichoplanin A isomers are vancomycin-type glycopeptide antibiotics for which the method is suitable (Table I).

Borghi discloses methods for separating the A2 factors of teichoplanin A2. Teicoplanin is obtained in a fermentate, extracted with an organic solvent, precipitated and applied to a Sephadex column to obtain teicoplanin A2. The various factors of teicoplanin A2 were obtained by subjecting

the product from the Sephadex column to reversed phase HPLC with a silanized silica gel 60 column that was eluted with ammonium formate/acetonitrile.

Strazzolini teaches that antibiotics closely related to teicoplanin are purified on reversed phase silanized silica gel having a distribution particle range of 0.06-0.2 mm used a ammonium formate/acetonitrile solvent (col. 3, lines 30-50). The antibiotics can be identified on an ocatdecylsilane reversed phase silica gel matrix using a similar solvent system (col. 4, lines 32-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to purify teicoplanin A2 from a fermentate by purification steps of containing with an adsorbent resin, followed by chromatography on a cation exchange resin and subsequent purification of reversed phase HPLC with the claimed resins and solvent systems. The ordinary artisan would have been motivated to do so because the claimed purification techniques: adsorbent resin chromatography, cation exchange and reversed phase chromatography are techniques well known to the ordinary artisan that have each been applied to the purification of teicoplanin or the class of vancomycin-type antibiotics of which teicoplanin is a recognized member. Recently, the Supreme Court commented on the validity of the "obvious to try" motivation:

> Narrow conception of obviousness inquiry, reflected in appellate court's application of "teaching, suggestion, or motivation" test, resulted in erroneous conclusion that summary judgment of obviousness should be vacated, since decision was based on erroneous holding that courts and patent examiners should look only to problem that patentee was trying to solve, and on erroneous assumption that person of ordinary skill in art attempting to solve problem will be led only to those elements of prior art designed to solve same problem, since court erroneously concluded that patent claim cannot be proved obvious merely by showing that combination of elements was "obvious to try," and since appellate court drew wrong conclusion from risk of courts and patent examiners falling prey to "hindsight" bias, in that rigid application of preventative rules that deny fact finders recourse to common sense are neither necessary nor consistent with precedent.
>
> Fact that claimed combination of elements was "obvious to try" might show that such combination was obvious under 35 U.S.C. §103, since, if there is design need or market pressure to solve problem, and there are finite number of identified, predictable solutions, person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation. KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)

The claimed invention is a combination which only unites old elements with no change in their respective functions and obviously draws on what is already known into the field. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

In the KSR decision, the Court further elaborated:

> Three cases decided after *Graham* illustrate the application of this doctrine. In *Anderson's-Black Rock, Inc.* v. *Pavement Salvage Co.*, 396 U.S. 57 [163 USPQ 673] (1969), the Court elaborated on this approach. The subject matter of the patent before the Court was a device combining two pre-existing elements: a radiant-heat burner and a paving machine. The device, the Court concluded, did not create some new synergy: The radiant-heat burner functioned just as a burner was expected to function; and the paving machine did the same. The two in combination did no more than they would in separate, sequential operation. *Id.*, at 60–62. In those circumstances, "while the combination of old elements performed a useful function, it added nothing to the nature and quality of the radiant-heat burner already patented," and the patent failed under §103. *Id.*, at 62 (footnote omitted).
> Finally, in *Sakraida* v. *AG Pro, Inc.*, 425 U.S. 273 [189 USPQ 449] (1976), the Court derived from the precedents the conclusion that when a patent "simply arranges old elements with each performing the same function it had been known to perform" and yields no more than one would expect from such an arrangement, the combination is obvious. *Id.*, at 282.
> The principles underlying these cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida* and *Anderson's-Black Rock* are illustrative—a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

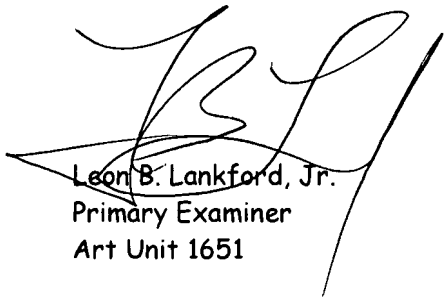
In the instant case, one of ordinary skill in the art would have recognized that the claimed purification steps are each known in the art for purifying teicoplanin A2 and other members of the group of vancomycin-type antibiotics. It is within the skill of the ordinary artisan to perform multiple-step purification schemes as suggested by Sawai (using two or more techniques *supra*). Thus, ordinary artisan would have reasonable expected that the combination of known purification techniques would have added together to give an improved, additive purity of the final product.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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